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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,407	11/14/2003	Robert J. Dunki-Jacobs	END-5005NP	9912

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EXAMINER	
ROZANSKI, MICHAEL T	
ART UNIT	**PAPER NUMBER**
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,407	DUNKI-JACOBS ET AL.	
	Examiner	Art Unit	
	Michael Rozanski	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. ***Claims 1, 2, and 4-18*** are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Kovacs et al*** (5,833,603) in view of ***Adair et al*** (US 6,750,037).

Kovacs et al disclose a system and method for detecting tissues comprising a capsule comprising a detector, a substance for associating with a target tissue where the substance is capable of being detected by the detector and a machine for verifying at least one of the detector and substance are suitable for use (col. 3, line 10 - col. 4, line 59; col. 6, lines 8-56). Kovacs et al further disclose the steps of verifying at least one component and concentration (amount of chemical or biochemical substance) of the physical properties of the tissue, cell, and biochemical components of region of interest. Although, Kovacs et al do not explicitly state that the detection substance is a monoclonal body, peptide, nanoparticle, mRNA and DNS corresponding to a generic

monoclonal antibody, and liposome, these are inherent properties of biochemical composition of the tissues and cells (col. 6, lines 26-36). In addition, Kovacs et al disclose that the biosensor detects energy spectra via optical or photosensor, which is used along with dye to acquire optical radiation. Although Kovacs et al do not explicitly state use or radioisotopes, the dye solution with radiation optical acquisition is inherent that the dye solution must be radioactive or radioisotopes (col. 1, lines 56-65; col. 4, lines 34-44; col. 5, lines 5-26). Furthermore, Kovacs et al disclose the method above where the sensor is a spectrophotometer acquiring multiple images of data from a region of interest with predetermines spectrum, wavelengths, and position to detect optical spectrum, i.e. spatial response pattern (col. 1,line 66 - col. 2, line 11).

First, it is known in the art that cancer cells are known to have a higher affinity for certain positron-emitting radioactive substances. However, it is not specifically disclosed in Kovacs et al that the substance for associating with a target tissue has an affinity for a target cell type. In the same field of endeavor, Adair et al teach of a method of cancer screening including introducing a compound to a patient for cell uptake, wherein cancerous cells have a natural affinity for the compound. The compound has a first portion, which creates a fluorescent marker and a second portion in the form of a radioisotope which creates a radioactive marker in targeted cells (col. 18, lines 45-53). It would have been obvious to one skilled in the art at the time the invention was made to have incorporated teaching of Adair et al in order to enable specific binding to cancerous cells for improved diagnosis and treatment.

4. ***Claim 3*** is rejected under 35 U.S.C. 103(a) as being unpatentable over ***Adair et al*** in view of ***Iddan et al*** (US 5,604,531) and ***Goldenberg*** (US 5,716,595).

Adair et al disclose a method of cancer screening including introducing a compound to a patient for cell uptake (i.e. binding to target cell type), wherein cancerous cells have a natural affinity for the compound. The compound has a first portion, which creates a fluorescent marker and a second portion in the form of a radioisotope which creates a radioactive marker in targeted cells (col. 18, lines 45-53). Adair et al disclose material bound to target cell, but do not specifically disclose a clearing agent. In the same field of endeavor, Goldenberg teaches of clearing agent for removing material not bound to the target cell type (col. 5, lines 1-8). It would have been obvious to one with ordinary skill in the art at the time the invention was made to incorporate teaching of Goldenberg in order to eliminate excess targeting material.

Adair et al also do not disclose a swallowable capsule or that the capsule material is coated to allow the capsule to goes through the gastro-intestinal (GI) tract. However, this deficiency is well known in the art where Iddan et al teaches a capsule detector where the device is swallowable and coated with material to allow the detector to pass through the GI tract. In addition, a reception system 12 is used with data processor 14 and position monitor 16 for tracking the position of the detector in the naturally occurring body lumen (col. 1, lines 34-40; col. 3, line 8 - col. 5, line 6). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Kovacs et al's teachings as described above with

Iddan et al's device designed to be swallow through the GI tract to achieve the claimed invention.

5. ***Claims 19-20*** are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Kovacs et al*** as in view of ***Adair et al*** and ***Iddan et al*** (US 5,604,531).

Kovacs et al disclose a system for detecting tissues comprising a capsule comprising a detector, a substance for associating with a target tissue where the substance is capable of being detected by the detector and a machine for verifying at least one of the detector and substance are suitable for use (col. 3, line 10 - col. 4, line 59; col. 6, lines 8-56). In addition, Kovacs et al disclose that the capsule includes multiple detectors, a radiation detector, magnetic detector, and single analyzer for each detector (col. 4, lines 35-44). Adair et al disclose a method of cancer screening including introducing a compound to a patient for cell uptake, wherein cancerous cells have a natural affinity for the compound. The compound has a first portion, which creates a fluorescent marker and a second portion in the form of a radioisotope which creates a radioactive marker in targeted cells (col. 18, lines 45-53). Although Kovacs et al disclose implantation of the sensor device, neither Kovacs et al nor Adair et al disclose that the capsule is a swallowable or that the capsule material is coated to allow the capsule to goes through the gastro-intestinal (GI) tract. However, this deficiency is well known in the art where Iddan et al teaches a similar capsule detector where the device is swallowable and coated with material to allow the detector to pass through the GI tract. In addition, a reception system 12 is used with data processor 14 and position

monitor 16 for tracking the position of the detector in the naturally occurring body lumen (col. 1, lines 34-40; col. 3, line 8 - col. 5, line 6). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Kovacs et al's teachings as described above with Iddan et al's device designed to be swallow through the GI tract to achieve the claimed invention.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER